

CLAIMS

1. A method of treating cancer comprising administering glufosfamide and gemcitabine in combination to a subject in need of treatment for cancer.

5 2. The method of claim 1 wherein the cancer is a locally advanced and/or metastatic solid tumor.

3. The method of claim 1 wherein the cancer is pancreatic cancer.

10 4. The method of any one of claims 1-3 wherein glufosfamide is administered for one or more dosage cycles, each cycle comprising an infusion of glufosfamide in the range of:

a) about 1.5 to about 8.0 g/m²; about 1.5 to about 6.0 g/m²; about 1.5 to about 4.5 g/m²; about 4.5 to about 8.0 g/m²; about 4.5 to about 6.0 g/m²; or about 4.5 to about 5.0 g/m² or over an infusion period of 1-6 hours once every three weeks;

15 b) about 1.5 to about 3.0 g/m² or about 1.5 to about 2.0 g/m² over an infusion period of 1-6 hours for three consecutive days (days 1, 2 and 3) every three weeks;

c) about 1.5 to about 2.0 g/m² over an infusion period of 1-6 hours once per week;

or

20 d) about 1.5 to about 8.0 g/m²; about 1.5 to about 6.0 g/m²; or about 1.5 to about 4.5 g/m² over an infusion period of 1-6 hours once every four weeks.

5. The method of any of claims 1-4 wherein gemcitabine is administered once each week of a seven-week dosage cycle, wherein said administration is for one or more seven-week cycles, and wherein each cycle comprises an infusion of gemcitabine of:

25 a) about 1000 mg/m² over a period of about 30 min;

b) about 2200 mg/m² over a period of about 30 min; or

c) about 1500 mg/m² over a period of about 150 min.

6. The method of any of claims 1-4 wherein gemcitabine is administered weeks 1, 2 and 3 of a four-week cycle for one more four-week cycles, and wherein each cycle comprises an infusion of gemcitabine of:

30 a) about 1000 mg/m² over a period of about 30 min;

b) about 2200 mg/m² over a period of about 30 min; or

c) about 1500 mg/m² over a period of about 150 min.

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7. The method of claim 6 or claim 7 wherein cycle comprises an infusion of glufosfamide in the range of about 1.5 to about 4.5 g/m² over an infusion period of 1-6 hours once every four weeks.

8. The method of claim 7 wherein gemcitabine is administered on the same day as the administration of glufosfamide.

9. The method of claim 10 wherein gemcitabine is administered between about 30 minutes to about 4 hours after the administration of glufosfamide.

10. A method of treating locally advanced and/or advanced metastatic advanced solid tumor comprising administering glufosfamide and gemcitabine in combination to a subject in need of such treatment wherein glufosfamide is administered for one or more dosage cycles, each cycle comprising:

a) an infusion of glufosfamide in the range of about 1.5 to about 8.0 g/m²; about 1.5 to about 6.0 g/m²; or about 1.5 to about 4.5 g/m² over an infusion period of 1-6 hours once every four weeks; and

b) an infusion of gemcitabine of about 1000 mg/m² over a period of about 30 min.

11. A method of treating pancreatic cancer comprising administering glufosfamide and gemcitabine in combination to a subject in need of such treatment wherein glufosfamide is administered for one or more dosage cycles, each cycle comprising:

a) an infusion of glufosfamide in the range of about 1.5 to about 8.0 g/m²; about 1.5 to about 6.0 g/m²; or about 1.5 to about 4.5 g/m² over an infusion period of 1-6 hours once every four weeks; and

b) an infusion of gemcitabine of about 1000 mg/m² over a period of about 30 min.

12. The method of claim 10 or claim 11 wherein each cycle comprises an infusion of glufosfamide in the range of about 1.5 to about 4.5 g/m² over an infusion period of 1-6 hours once every four weeks.

13. The method of claim 12 wherein gemcitabine is administered on the same day as the administration of glufosfamide.

14. The method of claim 13 wherein gemcitabine is administered between about 30 minutes to about 4 hours after the administration of glufosfamide.

15. The method of claim 14 wherein each glufosfamide is administered once every four weeks as an infusion in the range of about 1.5 to about 4.5 g/m² over an infusion period of 4 hours and gemcitabine is administered 30 minutes after the administration of glufosfamide.

16. A method of treatment comprising administering glufosfamide to a subject in need of treatment for a chemotherapy-refractory pancreatic cancer.

17. A method of treatment comprising administering glufosfamide to a subject in need of treatment for a gemcitabine-refractory pancreatic cancer.

18. The method of claim 16 or claim 17 wherein glufosfamide is administered for one or more dosage cycles, each cycle comprising an infusion of glufosfamide in the range of:

a) about 1.5 to about 8.0 g/m²; about 1.5 to about 6.0 g/m²; about 1.5 to about 4.5 g/m²; about 4.5 to about 8.0 g/m²; about 4.5 to about 6.0 g/m²; or about 4.5 to about 5.0 g/m² or over an infusion period of 1-6 hours once every three weeks;

b) about 1.5 to about 3.0 g/m² or about 1.5 to about 2.0 g/m² over an infusion period of 1-6 hours for three consecutive days (days 1, 2 and 3) every three weeks;

c) about 1.5 to about 2.0 g/m² over an infusion period of 1-6 hours once per week; or

d) about 1.5 to about 8.0 g/m²; about 1.5 to about 6.0 g/m²; or about 1.5 to about 4.5 g/m² over an infusion period of 1-6 hours once every four weeks.

19. A method of treating gemcitabine-refractory pancreatic cancer comprising administering glufosfamide to a subject in need of such treatment wherein glufosfamide is administered for one or more dosage cycles, each cycle comprising an infusion of glufosfamide in the range of about 1.5 to about 6.0 g/m² over an infusion period of 1-6 hours once every three weeks.

20. The method of claim 19 wherein glufosfamide is administered for one or more dosage cycles, each cycle comprising an infusion of about 4.5 g/m² glufosfamide over an infusion period of 1-6 hours once every three weeks.

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